No. 96-705

Supreme Court, U.S.
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IN THE
Supreme Court of the United States
OCTOBER TERM, 1996

COMMITTEE OF DENTAL AMALGAM ALLOY MANUFACTURERS AND DISTRIBUTORS AND DENTSPLY INTERNATIONAL INC.,

Petitioners,

v.

RICHARD A. BECKER, DIRECTOR OF THE OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT, DANIEL E. LUNGREN, ATTORNEY GENERAL OF THE STATE OF CALIFORNIA, AND ENVIRONMENTAL LAW FOUNDATION,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

PETITIONERS' REPLY BRIEF IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

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RULE 29.6 STATEMENT

Petitioners' Rule 29.6 statements filed with the petition for writ of certiorari are accurate and need not be amended to make them current.

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The critical issues before the Court are whether the Ninth Circuit's conflict in principle with numerous other circuits regarding preemption standards under the Federal Food, Drug, and Cosmetic Act ("FDCA") and the national significance of this case justify Supreme Court review. Instead of focusing on these issues, the state respondents primarily argue the merits of their case. Their approach effectively concedes many of the arguments in the petition.

Stripped of its rhetoric, respondents' analysis *confirms* that there is a substantial conflict in principle among the circuits regarding the scope of preemption under the FDCA: the Ninth Circuit's decision conflicts with the decisions of seven other circuits regarding the types of state requirements that are subject to preemption and also conflicts with four other circuits' decisions regarding the types of federal requirements that have preemptive effect. Although respondents repeatedly assert that *Medtronic, Inc.* v. *Lohr*, 116 S. Ct. 2240 (1996), resolves the conflict, they do not explain how, and they do not even *respond* to petitioners' compelling arguments to the contrary. Furthermore, respondents never deny that the conflict in principle has resulted in great differences from circuit to circuit in the scope of state regulatory power over medical devices, disrupting the device industry to the detriment of the consuming public.

Respondents also ignore or sidestep petitioners' arguments that this case has national significance. They do not contest that the Ninth Circuit has eviscerated the FDCA preemption provision, virtually eliminating preemption of medical device regulation by the nation's most populous State. And they also never deny that if the Ninth Circuit's ruling is allowed to stand, the FDA's decision to assign a medical device to Class I (thereby permitting its manufacture and marketing subject to the lowest level of federal statutory controls), and to reject direct consumer warnings in favor of other warnings to prescribers of the device, would have no

legal significance for any state government. Instead, state governments would be allowed to impose any requirements they like under statutes like Proposition 65, even if they conflicted directly with federal law, and even if they involved ad hoc "bounty hunter" actions by private parties.

Because respondents have not refuted petitioners' substantial arguments favoring Supreme Court review in this case, the Court should grant the petition.[1]

ARGUMENT

I. THE COURT OF APPEALS DECISION ESTABLISHES PREEMPTION STANDARDS THAT CONFLICT WITH THE STANDARDS IN OTHER CIRCUITS

The petition makes clear that the Ninth Circuit's decision confirms a substantial conflict in principle among the circuits concerning the scope of federal preemption under the FDCA. There is a conflict in principle with seven other circuits regarding the types of state requirements that are subject to preemption, and a conflict in principle with four other circuits regarding the types of federal requirements that have preemptive effect. Petition for writ of certiorari ("Pet.") at 13. Respondents argue that the decision below cannot conflict with any of these cases from other circuits, because they (1) involve state common law requirements rather than state statutes; (2) involve different federal requirements than the present case; and (3) predate *Lohr*. Respondents' brief in opposition to petition for writ of certiorari ("Opp.") at 20-26. This Court should reject respondents' analysis and conclude that there is a conflict in principle that justifies review.

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[1] Respondent Environmental Law Foundation did not file a brief in opposition to the petition.

A. A Conflict in Principle with Product Liability Cases from Other Circuits Justifies Review

Respondents first assert that there is no *direct* conflict with the product liability decisions in other circuits identified by petitioners, because the present case involves a state *statute*. Opp. at 23-24. This argument merely restates the obvious point, noted by petitioners (see Pet. at 13), that this case involves a "conflict in principle" rather than a "direct conflict" between holdings. Respondents do not dispute that the Ninth Circuit's test for identifying preempted state requirements is wholly inconsistent with the tests adopted by seven other circuits, see Pet. at 13-15, or explain why this conflict in principle might be an insufficient basis for Supreme Court review.

Indeed, respondents completely fail to confront a critical reason why this conflict in principle is particularly significant—it *derives from, and entrenches*, a substantial "direct conflict" created by earlier Ninth Circuit decisions that *did* involve product liability cases. See Pet. at 15-18, 20-21. Respondents explicitly acknowledge this direct conflict involving Ninth Circuit law, see Opp. at 24, and they do not deny that the court below applied the same Ninth Circuit standards, or that the Ninth Circuit's standards conflict with those adopted by other circuits.[2] Respondents also never contest that these conflicting preemption standards have cre-

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[2] Respondents suggest that the present case is not a proper vehicle for Supreme Court review of these preemption standards, because the "direct conflict" was created by an earlier Ninth Circuit case that this Court declined to review. See Opp. at 22 & n.10 (discussing *Kennedy* v. *Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995), cert. denied, 116 S. Ct. 2579 (1996)). This argument does not withstand scrutiny. Because this Court frequently allows a conflict to "percolate" for some period of time to allow the lower courts' positions to mature, it may not grant certiorari in the very first case that establishes the conflict.

ated a confusing and disjointed pattern of regulatory requirements that disrupt the rational and efficient development, production and sale of critical medical products (see Pet. at 21-22). Given the dramatic differences among the circuits concerning the scope of state regulatory power over medical devices, this Court should decide, as it has on many occasions in the past, that a conflict in principle is sufficient basis for granting review.

The Court also should reject respondents' assertion that "any conflicts concerning preemption of particular common law claims can only be resolved in the context of cases raising the same or similar common law claims." Opp. at 25. To the contrary, this case is an ideal vehicle to resolve the conflict regarding the standards for identifying state requirements that are subject to preemption.

Respondents ignore the fact that five Justices of this Court have explicitly confirmed that preemption analysis under the FDCA does *not* depend on the source of state law, and that the FDCA preemption provision treats state requirements the same regardless of whether they derive from statutes or common law doctrines. See Pet. at 14 n.7.[3] In addition, respondents' own analysis confirms that the source of state law is irrelevant to the preemption analysis. Their merits arguments are fundamentally assertions that this

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[3] Justice O'Connor's opinion in *Lohr*, which garnered four votes, made clear that the FDCA preemption provision "clearly pre-empts any state common-law action that would impose a requirement different from, or in addition to, that applicable under the FDCA—*just as it would pre-empt a state statute or regulation that had that effect.*" 116 S. Ct. at 2263 (emphasis added). In a separate opinion, Justice Breyer agreed that "ordinarily, insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, *it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action.*" *Id.* at 2260 (emphasis added).

Court's analysis in a *product liability* case (i.e., *Lohr*) required the result reached by the court below in a case involving a *state statute*. Thus, the opposition brief asserts repeatedly that the Ninth Circuit decision was "based directly on" *Lohr* (Opp. at 3), "closely tracked both the reasoning and holdings" of *Lohr* (*id.* at 12, 28), "addresses the same statute and regulations that were at issue" in *Lohr* (*id.* at 2), and "is absolutely consistent with this Court's opinion" in *Lohr* (*ibid.*).[4] These arguments concede that the source of state law does not change preemption analysis and confirm that the present case is a proper vehicle for resolving the conflict in principle with product liability cases from other circuits.

B. Review Is Justified by a Conflict in Principle with Cases from Other Circuits Involving Different Federal Requirements

This Court also should reject respondents' argument that there can be no conflict between the present case and the other cases identified in the petition, because the other circuits' cases involve federal requirements other than the prescription device labeling regulation, 21 C.F.R. 801.109. Opp. at 22. In advancing this argument, respondents once again imply that Supreme Court review is not appropriate without a "direct conflict" between cases interpreting the same requirement. *Id.* at 21. Yet respondents do not even refer to the Ninth Circuit's conflict in principle with four

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[4] Respondents further underscored the applicability of product liability decisions in the present case by filing an *amicus curiae* brief in *Lohr*. See Opp. at 3 n.1. The brief is exclusively devoted to a discussion of the potential impact a decision in *Lohr* would have in the present case. The brief predicted accurately that "while this [*Lohr*] Court is faced with the preemption of common law claims, its rulings may equally affect state statutory enactments like Proposition 65." Brief amicus curiae of the State of California in support of respondents/cross-petitioners Lora Lohr and Michael Lohr at 10-11, *Medtronic, Inc. v. Lohr*, No. 95-754 (filed Mar. 12, 1996).

other circuits, created by completely inconsistent tests for preemptive federal requirements.[5] See Pet. at 18-19. As the discussion above indicates, the conflict in principle explained in the petition should compel this Court to grant review.

C. *Medtronic, Inc.* v. *Lohr* Did Not Resolve the Conflict in Principle Regarding the Scope of FDCA Preemption

This Court also should reject respondents' assertion that "any conflicts exist only with cases that predate [*Lohr*] and are therefore no longer necessarily good law," and that "there is no conflict" because "no other circuit court has had the opportunity to apply" guidance from *Lohr*. Opp. at 20.

First, this Court should reject respondents' assertion that there is no conflict among the circuits regarding preemptive federal requirements, because this case is the only post-*Lohr* decision to address the preemptive scope of the prescription device labeling regulation. Opp. at 21. Respondents' argument is based on the erroneous premise that pre-*Lohr* cases regarding preemptive federal requirements are no longer good law. See Opp. at 20. Respondents give absolutely no explanation *why* the decisions from four other circuits cited in the petition are no longer good law, and respondents do not even address the reasons, advanced by petitioners, that those decisions are still valid following *Lohr*. See Pet. at 20-21. Instead, respondents argue that two *other* circuit cases *not* cited in the petition are no longer good law, because they conflict with *Lohr*. Opp. at 21 n.8. Yet the conflict in principle identified in the petition does not involve these other

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[5] Respondents and petitioners disagree about the scope of the test for preemptive federal requirements adopted by the court below. Compare Pet. at 18-19 with Opp. at 14. However, respondents never even suggest that their interpretation of the Ninth Circuit's test resolves the conflict with the tests adopted by the other circuits.

cases; respondents' argument therefore does not withstand scrutiny.[6]

Second, this Court should reject respondents' argument that there is no conflict regarding the test for preempted state requirements following *Lohr*. See Opp. at 20. Respondents suggest erroneously that pre-*Lohr* decisions regarding state law requirements are no longer good law. *Id.* Respondents' arguments ignore the fact that *Lohr* supports the continued validity of cases from seven circuits establishing the conflict in principle, because five Justices confirmed that "generally applicable" common law requirements are subject to preemption under the FDCA. See Pet. at 15-16. Instead of addressing the opinions of these Justices, respondents rely exclusively on passages from Justice Stevens' opinion, which they assert should foreclose preemption of generally applicable state requirements. See Opp. at 15, 24. In so doing, respondents merely confirm that the different *Lohr* opinions lack consistency on some issues (see Pet. at 15-16 & n.10)—respondents do *not* establish that the cases cited by petitioners are bad law. Indeed, given the inconsistencies in *Lohr*, this Court should review this case to clarify these issues in the best interests of the device industry and the consuming public.

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[6] In their argument on the merits, respondents also suggest incorrectly that *Lohr* resolved the question of preemption in this case by holding that the prescription device labeling regulation did not preempt state law requirements. See Opp. at 14. This argument overlooks the fact that the *Lohr* holding was limited to the particular common law claims at issue in that case; this Court made clear that in other cases, an individualized comparison between other particular state and federal requirements will be necessary to make a ruling on the merits of the preemption issue. See Pet. at 20 & n.15. Respondents also completely ignore the fact that there are federal requirements other than the prescription device labeling regulation that could preempt the Proposition 65 warnings in this case. See *id.* at 6-8.

II. THIS CASE PRESENTS AN IMPORTANT FEDERAL QUESTION THAT HAS NOT BEEN, BUT SHOULD BE, SETTLED BY THIS COURT

This case presents the Court with a superb opportunity to define for the first time the critical balance of state and federal regulatory power over medical devices. In particular, a decision in this case would address the scope of state regulatory power when the FDA regulates by assigning a device to Class I (because more stringent controls are unnecessary to provide reasonable assurance of safety and effectiveness)[7] and deliberately declines to impose additional requirements in formal agency proceedings. Respondents' only reply is a simplistic observation that the FDA has the authority to preempt state regulatory power if it so desires. See Opp. at 26. But this response begs the question, which is whether the Agency's regulatory decision described above—albeit a passive one—has preemptive effect.[8]

Moreover, respondents' argument does not detract from the significance of the case, which itself justifies Supreme Court review. See Pet. at 23-24. The Ninth Circuit's test for

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[7] See Pet. at 4.

[8] In one of their arguments on the merits, respondents assert that agency inaction cannot preempt state law, because the FDCA requires a federal "requirement" for preemption to occur, and inaction does not yield a requirement. See Opp. at 16-20. This argument misses the point. Petitioners agree that there can be no preemption without an applicable federal requirement. If review is granted, petitioners will argue that the Proposition 65 warnings are preempted, because they are "different from, or in addition to," extensive federal requirements that *do* apply to dental mercury, when those requirements are considered in conjunction with the FDA's affirmative rejection of additional reproductive toxicity warnings. See Pet. at 6-8 (describing federal requirements), 20 n.15 (describing preemptive effect of federal requirements in context of FDA's rejection of reproductive toxicity warnings).

preemption will virtually *never* invalidate state law. See Pet. at 2. If the Ninth Circuit's decision is allowed to stand, then the States of that circuit will be permitted to impose virtually any requirement they desire on FDA-regulated medical devices, even if the state requirement directly conflicts with federal law. See Pet. at 26.

Furthermore, this case is an appropriate vehicle to review the important federalism issues at stake, because the assertion of regulatory power by the State of California under the Proposition 65 "bounty hunter" clause is particularly extensive, affecting the ability of numerous national manufacturing companies to distribute products through interstate commerce into the nation's largest market. See Pet. at 25-26. Respondents do not refute this fact, arguing only that the "bounty hunter" provisions of this state statute are also present in federal statutes not relevant to this case. See Opp. at 9, 27. Respondents do not even respond to the argument that this extraordinarily broad assertion of state power provides an excellent context for review of the issues presented. Nor do they address the national controversy that is raging from the attempts by "bounty hunters" to apply Proposition 65 requirements that conflict with federal law.[9]

Finally, respondents say little to address petitioners' argument that this case is worthy of Supreme Court review, because Proposition 65 may require warnings that violate federal law. See Pet. at 26. Although respondents make

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[9] The petition noted that the national significance of the preemption issue is confirmed by pending OSHA proceedings considering preemption of Proposition 65 warnings. See Pet. at 26 n.17. In the short time since the petition was filed, over 150 manufacturing companies and ten national trade associations (representing thousands of national manufacturers) have filed comments in those OSHA proceedings, confirming that Proposition 65 "bounty hunter" suits are having a significant impact on companies that do business in all fifty States.

various claims to discount the significance of the federal government report that petitioners cite for this proposition (see Opp. at 27-28), they never deny that the FDA's parent agency, the Department of Health and Human Services, issued this formal report, authored in part by FDA personnel, stating that federal law *prohibits* the types of warnings that are currently being *required* under state law through Proposition 65 "bounty hunter" suits. See Pet. at 26. They also never deny the underlying logic of petitioners' argument: if the FDA determines that there is no legitimate scientific basis for reproductive toxicity warnings, the general controls provisions of the FDCA barring misleading labeling would prevent manufacturers from adding the warnings. See Pet. at 8 (citing 21 U.S.C. 352(a), 321(n)). This direct clash between state and federal requirements justifies Supreme Court review of this case.

CONCLUSION

This Court should grant the petition for certiorari.

Respectfully submitted,

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